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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
This Document Relates to:	:	
	:	
Graves v. Merck & Co., Inc.	:	
	:	
Case No: 1:06-cv-05513-JFK	:	

DEFENDANT MERCK SHARP & DOHME CORP.'S MEMORANDUM IN SUPPORT OF ITS RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

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Defendant Merck Sharpe & Dohme Corp. ("Merck") files this renewed memorandum at the close of all evidence in support of its Motion for Judgment as a Matter of Law pursuant to Federal Rule of Civil Procedure 50(a) ("Rule 50(a)").

INTRODUCTION

The Court denied Merck's motion for judgment under Rule 50(a) made at the close of its case. Merck renews the grounds made in that motion, which are set forth again below. Merck contends that while all of its grounds are valid, the Court should pay particular attention to the first ground before instructing the jury and giving this case to them for deliberation, which further describes why there is no valid basis upon which Plaintiff's strict liability design defect claim may stand because of the utter absence of evidence that Plaintiff was an intended user of Fosamax.

STANDARD OF REVIEW

A motion for judgment as a matter of law under Rule 50(a) should be granted if "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a).

ARGUMENT

1. Plaintiff's strict liability design defect claim fails as a matter of law because Plaintiff has not established that she was an intended user of Fosamax.

In Plaintiff's opposition to the Rule 50(a) motion made by Merck at the close of her case, Plaintiff responded to this identical ground by accurately describing how Florida law "distinguish[es] the standard applied in a strict liability design defect claim from the standard applied in a negligent design defect claim, holding that a manufacturer is strictly liable for injuries caused ***to an intended user*** of a reasonably (sic) dangerous product while it may be

liable under a theory of negligent design defect for injuries caused ***to a foreseeable user*** of an unreasonably dangerous product." (50 (a) Opp. at 1 citing *Jennings v. BIC Corp.*, 181 F.3d 1250, 1256 (11th Cir. 1999) (emphasis supplied).)

The distinction between an intended user -- the strict liability standard -- and a foreseeable user -- the negligence standard -- in the design defect context comes from the fact that the strict liability cause of action is grounded in the Restatement (Second) of Torts, while the negligence cause of action is a common law cause of action and does not. In 1992, the Florida Supreme Court considered the question whether strict liability could apply where the use of a product was arguably foreseeable, but was not intended. The Court found that it could not, observing:

> Florida adopted the principles of strict liability in tort under section 402A of the *Restatement (Second) of Torts* in *West v. Caterpillar Tractor Co.*, 336 So.2d 80 (Fla.1976). In order for strict liability to apply to the manufacturer, the transformers in this instance must have been used for the purpose intended.

High v. Westinghouse Elec. Corp., 610 So.2d 1259, 1262 (Fla. 1992).

Seven years after the Florida Supreme Court's decision in *High*, the Eleventh Circuit Court of Appeals in *Jennings* determined that the unintended use doctrine applied equally when the question was applied to an unintended use**r**. In that suit involving strict liability and negligent design defect claims against the manufacturer of a cigarette lighter, the court of appeals held that the negligent design defect claim could potentially stand based on the child's use of the lighter, but the strict liability claim could not: "Since use of a lighter as a children's plaything was not its intended use, the manufacturer is not strictly liable for injuries incurred when it is so used, ***even if such use was reasonably foreseeable by BIC***.... [A]lthough BIC is not strictly liable for the injury caused by its product in this case, it could still be liable if it was negligent in failing to design child-proof features into its lighters." 181 F.3d at 1256

Since *High* and *Jennings*, other courts applying Florida law have held that manufacturers may not be held liable for strict liability design defect absent a showing that the use was intended, while leaving open the issue of foreseeability. *See Veliz v. Rental Service Corp.*, 313 F. Supp. 2d 1317, 1326 (M.D. Fla. 2003) ("Since use of the Lull 844C-42 Telescopic Handler as a personnel lift was not its intended use, the Defendants here are 'not strictly liable for injuries incurred when it [was] so used, even if such use was reasonably foreseeable by [the Defendants]. Although the Defendants are not strictly liable for the injury caused by their product in this case, they could still be liable if they were negligent and their negligence proximately caused the decedent's injuries."); *Martin v. JLG Industries, Inc.*, 2007 WL 2320593 (M.D.Fla.) ("Since the evidence in this case shows that Plaintiff was not using the product as intended, the Court agrees that Plaintiff's misuse of the lift bars his strict liability defective design claim.... However, with respect to Plaintiff's negligent design claim, the Court finds that summary judgment is not appropriate.").

At the summary judgment stage in this case, Plaintiff argued that she could prove to the jury that she was a patient for whom Fosamax was indicated through a medical record showing she had "moderately low bone mass" while taking Fosamax. (Pl. Opp. to MSJ at 22). (*See also* 10/12/10 Hearing Tr. at 29:11-12 (claiming "she had a T-score of negative 1.1"). Plaintiff contended that this was relevant to either theory of why she was prescribed the drug, either under the glucocorticoid-induced osteoporosis ("GiOP") indication or the post-menopausal osteoporosis indication.[1] (Pl.'s Mem. Opp. MIL 4–5.)

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1. The only undisputed evidence presented at trial is that Dr. Adams prescribed Fosamax to Plaintiff to prevent her from developing GiOP:

   Q: OK. And tell me why it was you prescribed Fosamax for her in October 2001?

(Footnote continued on next page)

At trial, however, the only evidence Plaintiff presented about her bone mass during that timeframe was a record stating that she had "normal bone mineralization" and a *positive* T-score. Plaintiff has not presented any evidence that she had "low bone mineral density," under any definition of that term. To the contrary, the only evidence presented about her BMD prior to her date of injury was an October 2002 DEXA scan report showing that she had a positive T-score (BMD) of 1.1, which the report described as "**normal bone mineralization of the femur and upper lumbar spine**." (Pl. Ex. 30228.1) (emphasis added).[2] While Plaintiff raised for the first time the theory that her misreading of the relevant DEXA scan could be ignored and a "Wards Triangle" reading could somehow establish her low bone mineral density reading in her opposition to Merck's original 50(a) brief, such argument was completely unsupported by the evidence and was contrary to the uncontroverted testimony of Dr. Silverfield at trial. Thus, while the Court found at summary judgment that "there [w]as a factual dispute about whether or

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(Footnote continued from prior page)

A: I was concerned about bone loss because she was on steroid use – on chronic steroids. I was hoping that they would wean them – wean her off them, the steroids. Then it wouldn't be an issue. But when it became clear that her rheumatoid arthritis was severe – the severest case I've ever seen, and that she was going to be on steroids for a long time a long time, probably high doses, I thought we better protect her bones.

(Tr. 833:9-17).

2. The Fosamax label states in pertinent part:

INDICATIONS

…

• Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids ***in a daily dosage equivalent to 7.5 mg or greater of prednisone and who have low bone mineral density*** (see PRECAUTIONS, *Glucocorticoid-induced osteoporosis*).

(Def. Ex. A392) (emphasis added).

not Graves was prescribed Fosamax for an indicated use" (SJ at 22), the Court's finding at that stage of the proceedings has not been borne out at trial.[3] (Tr. 1770:23 - 1772:4.)

In sum, Plaintiff has not presented any evidence that Fosamax was *intended* to be used for treatment of GiOP in patients like her. Under Florida law, Plaintiff as an unintended user cannot arguably be held strictly liable for any injuries to Plaintiff caused by a claimed design defect in Fosamax and the Court should therefore enter judgment as a matter of law for Merck on Plaintiff's strict liability design defect claim.[4]

2. Plaintiff's negligent design defect claim fails as a matter of law because Plaintiff has not established that it was foreseeable that a physician would prescribe Fosamax for GiOP treatment in a patient such as Plaintiff.

Florida law permits a product manufacturer to be held liable for negligent design defect for injuries caused through an unintended use of a product only if that unintended use was reasonably foreseeable to the manufacturer. *Jennings v. BIC Corp.*, 181 F.3d 1250, 1257 (11th Cir. 1999). An unintended use is not reasonably foreseeable if the use does not comply with the product's written safety instructions. *Id.* (affirming summary judgment for cigarette lighter manufacturer because although it was foreseeable that children would get hold of lighters, it was not foreseeable that children would obtain lighters without involvement of adult and that adult would ignore safety instructions on the lighter).

The Court's summary judgment opinion indicated that it was possible that Plaintiff would present evidence that off-label use such as the use in this case was foreseeable. *In re Fosamax*

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3. While Merck also disputes whether Plaintiff's use was foreseeable, and whether as a matter of law foreseeable use of a prescription medicine can give rise to a cause of action for a Plaintiff prescribed the medicine for a non-indicated use, this part of the Court's analysis under its summary judgment order *In re Fosamax Prods. Liab. Litig*., 2010 WL 4273310, *9 (S.D.N.Y. Oct. 22, 2010) is a separate issue that is addressed at section II, below.

4. In the event the Court disagrees, Merck requests that the Court consider closely the proposed jury instructions and verdict form Merck has submitted that make clear Plaintiff's obligations under the law.

Prods. Liab. Litig., 2010 WL 4273310, *9 (S.D.N.Y. Oct. 22, 2010). But, Plaintiff has presented no evidence that Merck should have foreseen that physicians would prescribe Fosamax for GiOP treatment to patients who, like Mrs. Graves, did not fall within the approved GiOP indication. The Fosamax label makes it clear that a person should be on at least 7.5 mg of prednisone per day and have a low bone mineral density in order to meet the GiOP indication, as Dr Silverfield made crystal clear in his testimony. (Tr. 1767:24 - 1768:2.) Since Plaintiff failed to produce any evidence showing that it was foreseeable that Fosamax would be prescribed off-label, her negligent design defect claim fails as a matter of law.

3. Plaintiff has presented no evidence that Dr. Adams prescribed Fosamax to Plaintiff for prevention of postmenopausal osteoporosis.

Plaintiff will try to dodge the above-cited case law by contending that she did use Fosamax for an intended use because Dr. Adams also prescribed Fosamax to her for prevention of postmenopausal osteoporosis, as she did at summary judgment. But, Plaintiff has presented no evidence to support that allegation. In fact, since the Court ruled on Merck's motion at close of Plaintiff's case, the evidence before the court consistently from de Papp, Silverfield and Santora does nothing but support the fact that the prevention indication is not applicable to glucocorticoid users. They have consistently testified that glucocorticoid-induced osteoporosis is a separate disease state, and have repeatedly rejected Plaintiff's efforts to suggest that it is applicable to Mrs. Graves. For example:

Dr. de Papp testified:

> Q. And the last one we have here is: "Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dosage equivalent to 7.5 milligrams or greater of Prednisone and who have low bone mineral density." Do you see that?
>
> A. That's correct.
>
> Q. What does this refer to?

A. So, again, this is a separate indication. This is separate from either the treatment or prevention of post-menopausal osteoporosis because we're really referring to a different disease. Steroid-induced or, as described here, glucocorticoid-induced osteoporosis is a different disease that affects not only post-menopausal women using steroids but younger women and men, as this says, who are using steroids.

(Tr. 1064:20-1065:9)

Q. And we talked earlier that there is an indication for treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids. I want to ask you, is this disease state different than postmenopausal osteoporosis?

A. Yes, it is.

...

Q. Now, is the mechanism through which steroids cause osteoporosis, the same as the mechanism through which postmenopausal osteoporosis occurs?

A. No. It actually has some very fundamental differences, from postmenopausal osteoporosis.

(Tr. 1077:2-10; 1078:2-6)

Dr. Silverfield testified:

Q. Right? And you're aware that there is also an indication for the prevention of osteoporosis; true?

A. That's true.

Q. And you prescribe Fosamax to patients of yours for the prevention of osteoporosis consistent with that indication, don't you?

A. We do on occasion, yes.

Q. And some of the factors that you look at in that prevention indication is not just T scores, but whether the patient is at risk for developing osteoporosis; true?

A. That's true.

Q. And so you look at things like family history, right?

A. Yes.

Q. You look at things like, are they Caucasian; right?

A. Yes.

Q. You look at things like how big are they; in other words, are they frail or stocky?

A. That's true.

Q. And you look at things like what medications are they on that might cause a decrease in bone mineral density, don't you?

A. No, that's a separate category. If you're referring to corticosteroids, that's actually a separate category. That's what we talked about earlier, that's the GIOP. That's a different portion of the label, not to do a prevention. That's actually a different disease state.

(Tr. 1710:6-1711:9)

and Dr. Santora testified:

Q. Now, was there also testing done for patients who take glucocorticoids and develop osteoporosis as a result of that medicine?

A. Yes. There was a separate development program for that population. That included men or women, could have been younger or older, patients who were on high dose glucocorticoids and were at high risk of fractures. There were two phase three studies for that application, but that was entirely separate from the fracture intervention trial. Because glucocorticoid-induced osteoporosis has a lot of different risk factors and considerations. And the same drug might work well for glucocorticoid osteoporosis, yet not work well for postmenopausal osteoporosis and vice versa.

(Tr. 1856:9-22)

Q. And why were patients on glucocorticoids excluded from the FIT trial that Mucci was addressing?

A. Glucocorticoid-induced osteoporosis is a very different disease. It produces a different type of bone pathology or bone weakness from what is produced simply by the menopausal loss of estrogen. And it's -- it needs to be studied separately. Not only that, but men, young women, and as well as postmenopausal women, develop glucocorticoid-induced osteoporosis if they receive a high enough dose of those steroids for a long enough period of time.

(Tr. 1858:8-14)

Moreover, the only documentary evidence introduced since the time Plaintiff closed her case that further describes the reason why Dr. Adams prescribed Judith Graves Fosamax was a medical record introduced during Dr. Silverfield's testimony, which states "Discussed osteoporosis therapy 2nd [secondary to] chronic steroid use." (Trial Tr. 1669:4-17, Ex. C3.418.)

This completely supports the testimony introduced from Dr. Adams in Plaintiff's case-in-chief in which he testified:

> Q: OK. And tell me why it was you prescribed Fosamax for her in October 2001?
>
> A: I was concerned about bone loss because she was on steroid use – on chronic steroids. I was hoping that they would wean them – wean her off them, the steroids. Then it wouldn't be an issue. But when it became clear that her rheumatoid arthritis was severe – the severest case I've ever seen, and that she was going to be on steroids for a long time a long time, probably high doses, I thought we better protect her bones.

(Tr. 833:9-17).

In other words, Plaintiff presented no evidence that Dr. Adams prescribed Fosamax to Plaintiff for prevention of postmenopausal osteoporosis; he prescribed it for GiOP.

4. Plaintiff presented no evidence that for patients taking Fosamax for GiOP the risks outweigh the benefits.

In the *Boles* case, Mrs. Boles avoided judgment as a matter of law through Dr. Furberg's testimony that the "Mucci analysis" of Merck's four-year FIT clinical trial and the JAMA article by Dr. Cummings about that same clinical trial showed that Fosamax did not provide fracture reduction efficacy for women like Mrs. Boles. *In re Fosamax Prods. Liab. Litig.*, 2010 WL 3955814, *3 (S.D.N.Y. Oct. 4, 2010). Mrs. Graves relied on the same evidence. But, this case is different from *Boles* because, unlike Mrs. Boles and the patients in the FIT trial, Mrs. Graves took glucocorticoids.

Plaintiff did not present a single study or other piece of information regarding Fosamax's efficacy in patients on glucocorticoids. Indeed, Dr. Furberg admitted that FIT "did not include patients who were on steroids." (Tr. 897:16-23.) The Court itself asked Dr. Parisian whether "the FIT study ha[d] anything to do with women who were taking glucocorticoids," to which Dr.

Parisian responded "Not [t]he FIT study." (Tr. 734.). And, whenever Plaintiff presented evidence about the "Mucci analysis" and the Cummings paper, the Court instructed the jury:

> The Mucci Review and the Cummings article . . . are analysis of data from a clinical study called the Fracture Intervention Trial, or "FIT." The FIT study, the subject of the Mucci Review and the Cummings article, did not study patients who were taking glucocorticoids like Mrs. Graves was. The FIT study was not designed to determine Fosamax's efficacy for patients suffering from glucocortiocoid-induced osteoporosis."

(Tr. 681:19 – 682:2) (*See also* Tr.127, 732, 850 (giving same instruction)).

Plaintiff presented no evidence, let alone expert testimony, that the FIT trial, which specifically excluded patients taking glucocorticoids, can be used to determine the effect of the medicine on patients who do take glucocorticoids. Yet it was only the FIT trial – the subject of both the Mucci analysis and the Cummings article – upon which Dr. Furberg relied. Accordingly, the record is devoid of any evidence to establish that for patients taking the medicine in accordance with the GiOP Indication that the risks outweigh the benefits.

5. Unlike in the *Boles* trials, Plaintiff presented no evidence that she had ONJ as of the date of her claimed injury.

In the *Boles* case, the plaintiff avoided judgment as a matter of law through expert testimony that Mrs. Boles had ONJ by the date of her claimed injury – September 2003. *In re Fosamax Prods. Liab. Litig.*, 2010 WL 1257299, *3 (S.D.N.Y. March 26, 2010) (noting that "Dr. Hellstein opined that Plaintiff's jaw injury began as stage zero ONJ in August of 2002 and progressively worsened to stage three ONJ"); *In re Fosamax Prods. Liab. Litig.*, 2010 WL 3955814, *3 (S.D.N.Y. Oct. 4, 2010) (noting that Dr. Elwell "concluded that Plaintiff's use of Fosamax caused her to develop ONJ beginning in August 2002").

Mrs. Graves relied on Dr. Villaret to establish that she had ONJ caused by Fosamax. But, unlike the specific causation experts in the *Boles* trials, Dr. Villaret could not offer an opinion on whether Plaintiff had ONJ as of her claimed date of injury – March 2003.

> Q. Now, you do not know what the appropriate diagnosis for her would have been in June of 2004, correct?
>
> A. Correct.
>
> Q. The same would be true for 2003?
>
> A. True.

(Tr. 626.)

In sum, Plaintiff alleges that Fosamax caused her to suffer ONJ in March 2003. But, she has offered no expert testimony on her condition as of March 2003. For that reason alone, Merck is entitled to judgment as a matter of law.

6. Plaintiff's specific causation expert, Dr. Villaret, did not rule out other possible causes for Plaintiff's injury.

As this Court observed in the *Flemings* case, specific causation experts "must at least address obvious alternative causes" of plaintiff's injury "and provide a reasonable explanation for dismissing specific alternative factors identified by the defendant." *In re Fosamax Prods. Liab. Litig.*, 2009 WL 4042769, *8 (S.D.N.Y. Nov. 23, 2009).[5] Indeed, in *Flemings* the Court found that the testimony of the plaintiff's treating physician could not establish specific causation because the physician "did not rule out or otherwise address other possible causes for the injury to Plaintiff's jaw, such as trauma *or infection*." *Id.* at *8.

5. *See also Golod v. Hoffman La Roche*, 964 F. Supp 841, 859 (S.D.N.Y. 1997) ("When there are several risk factors that can explain a plaintiff's injury, the plaintiff must provide some evidence of why those other causes are inapplicable.")

Merck presented evidence of several alternative causes for Plaintiff's injury. For example, other treaters had diagnosed Plaintiff with osteomyelitis – an infection of the jaw bone. Dr. Villaret conceded that osteomyelitis can lead to dead, exposed jaw bone. (Tr. 609-610). And, Dr. Villaret conceded that he could not say that the treaters who diagnosed Plaintiff with osteomyelitis were wrong. (Tr. 635). Dr. Villaret also conceded that Plaintiff's Rheumatoid Arthritis medications suppressed her immune system. (Tr. 613). Dr. Villaret conceded that if at the time he diagnosed Plaintiff with ONJ he had known that Plaintiff had only taken Fosamax for 18 months at the onset of her injury, he would have considered "many of these alternate causes that we have been talking about today." (Tr. 626). Despite these and other possible causes of dead jaw bone, Dr. Villaret only testified that he ruled out cancer and granulomatous disease as possible alternative causes of her injury. (Tr. 573).

In sum, Merck presented alternative causes for Plaintiff's injury, and Plaintiff's specific causation expert did not rule out those causes. As a result, Merck is entitled to judgment as a matter of law.

7. Plaintiff alleged the "defect" in this case is the Fosamax label; however, Plaintiff did not present any evidence that a different label would have changed Dr. Adams' decision to prescribe Fosamax to her.

Plaintiff does not allege that Fosamax should be withdrawn from the market. To the contrary, in opening statement her counsel stated that Fosamax is a good medicine for some patients, (Tr. 123-24) and Dr. Furberg testified that Fosamax provides "dramatic benefit" for some patients, (Tr. 859).

Plaintiff claims that Fosamax is defective in its labeling. Indeed, Dr. Parisian's testimony focused almost exclusively on labeling. For example, Plaintiff's counsel and Dr. Parisian engaged in the following colloquy:

> Q: What is the purpose of the label, or prescriber information, for a prescription drug?
>
> A: The purpose of the label is to provide the pharmacist or the physician or healthcare provider prescribing the drug with the information that they need about the product to ensure that the product can be used safely and effectively for a patient, for treating a patient.

(Tr. 708:19-25). (*See also* Tr. 710:14-16 (Dr. Parisian testifying: "The manufacturer has a duty or a role to ensure that there is adequate information in there for a physician to determine whether to use the product."); Tr. 728:10:12 (Dr. Parisian agreeing that a manufacturer does not "need the permission of the FDA to make a change with respect to its *notice to physicians*") (emphasis added)).

And, according to Dr. Parisian, the Fosamax label did not accurately inform physicians of the benefits of Fosamax because it did not include the Mucci analysis.

> Q: Now, ma'am, during the timeframe of 2001 to the end of March 2003, did Merck's Fosamax label properly reflect the information that the company had regarding the relationship between Fosamax and its ability to prevent fractures?
>
> A: No, sir, it didn't.

(Tr. 733:14-22) (objections omitted). (*See also* Tr. 647:20-648:4 (Dr. Parisian testifying that Merck did not "meet its obligation" under federal regulations to update the Fosamax label); Tr. 728:14-19; 732:25 – 733:8 (Dr. Parisian testifying that the Fosamax label was not "accurate")).

Under Florida law, a plaintiff alleging a design defect must prove that the alleged defect was the proximate cause of her injury. *See, e.g.*, *West v. Caterpillar Tractor Co., Inc.*, 336 So.2d 80, 87 (Fla. 1976) (holding that "[i]n order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish," among other things, "the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection

between such condition and the user's injuries or damages").[6] In the context of prescription drugs, product labels are designed to be read by physicians, not patients. *See, e.g.*, *Hoffman-La Roche, Inc. v. Mason*, 27 So.3d 75, 77 (Fla. Ct. App. 2009) (noting that duty to adequately label prescription drugs "is directed to physicians rather than patients under the 'learned intermediary doctrine'"). In other words, the physician's decision to prescribe the medication is part of the causal chain of events. Therefore, where a plaintiff alleges that a prescription drug label was defective, she must prove that her physician would not have prescribed the medication to her if the manufacturer had provided a "non-defective" label (*i.e.*, a label containing different information). *See id.* (prescription drug plaintiff had burden to prove that "inadequacies" in the label were "the proximate cause" of his injury).

Despite Plaintiff's claim that the Fosamax label was defective, she presented no evidence that the addition of different information to the label would have changed Dr. Adams' decision to prescribe Fosamax. To the contrary, Dr. Adams testified that he still considers Fosamax to be a good medicine and he still prescribes it today. (Tr. 834).

As this Court is aware, Florida does not have a heeding presumption, which means that there is no presumption that a different product label would have affected the use of the product. *In re Fosamax Prods. Liab. Litig.*, 688 F. Supp. 2d 259, 265 (S.D.N.Y. 2010) (discussing difference between Florida law and Indiana law). Instead, the plaintiff has the burden of putting on affirmative evidence that a different label would have resulted in the plaintiff not using the product. *Id.* The scant three pages of Dr. Adams' testimony do not provide that evidence.

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6. *See also Wolicki-Gables v. Arrow Intern., Inc.*, 641 F. Supp. 2d 1270, 1285 (M.D. Fla. 2009) (design defect plaintiff must prove that "the product has a defect that renders it unreasonably dangerous and that the unreasonably dangerous condition is the proximate cause of the plaintiff's injury").

Therefore, Merck is entitled to judgment as a matter of law on both of Plaintiff's design defect claims.

8. Plaintiff has not established that Fosamax presented a foreseeable risk of ONJ as of March 2003.

Even if Plaintiff used Fosamax for an intended use, she has the burden to show that Fosamax presented a foreseeable risk of ONJ at the time Merck manufactured the Fosamax that allegedly caused her pre-March 31, 2003 injury. Indeed, Plaintiff conceded this point in her Complaint, which alleges that Merck should be held strictly liable for design defect because Fosamax's "*foreseeable* risks exceeded the benefits associated with the design or formulation." (Complaint at 4-5, ¶ 20) (emphasis added). *See also* Fla. Stat. Ann. section 768.1257 (in design defect cases, "the finder of fact shall consider the state of the art of scientific and technical knowledge and other circumstances *that existed at the time of manufacture*, not at the time of loss or injury") (emphasis added).[7] (*See also Boles I* Jury Charge at 35 and *Boles II* Jury Charge at 22 (instructing jury on strict liability design defect claim to "consider the feasibility of an alternative safer design given the scientific and technical knowledge that existed at the time of manufacture").[8]

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7. Although section 768.1257 is in the Negligence Chapter of the Florida Statutes, it applies to both negligent and strict liability design defect cases. *See Sta-Rite Industries, Inc. v. Levey*, 909 So.2d 901, 903-04 (Fla. 3d Dist. Ct. App. 2004) (applying section 768.1257 to strict liability design defect claim).

8. *See also Edic v. Century Prods. Co.*, 364 F.3d 1276, 1279-80 n.2 (11th Cir. 2004) (under Florida law, it is the "foreseeable" risk that is relevant to both negligent and strict liability design defect claims); *Sta-Rite Indus., Inc. v. Levey*, 909 So.2d 901, 903-04 (Fla. 3d Dist. Ct. App. 2004) (strict liability design defect claim was supported by the evidence because of the "reasonable forseeability" of the injury); *Adams v. G.D. Searle & Co., Inc.*, 576 So.2d 728, 733 (Fla. 2d Dist. Ct. App. 1991) (risk/benefit analysis for strict liability design defect claim examines "known" risk "as of the date the product is distributed"); Restatement (Third) of Torts: Products Liability § 6 cmt. g (1998) ("Duties concerning the design and marketing of prescription drugs and medical devices arise only with respect to risks of harm that are reasonably foreseeable at the time of sale.").

Plaintiff is required to show foreseeability through expert testimony. *See Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1067 n.4 (S.D. Ill. 2007) ("What a drug manufacturer knew or should have known is a question of fact, which a plaintiff must establish by expert testimony.") (citation omitted). Plaintiff relied on Dr. Goss to support her general causation claim that Fosamax presents a risk of ONJ. However, in so testifying, Dr. Goss directly undercut the fact that Plaintiff was obligated to establish that this risk was foreseeable before March 2003. To the contrary, Dr. Goss testified that his letter to the editor of the Australian Dental Journal published in "late 2003" was the "first publication identifying in the published domain, a report of [ONJ] in a Fosamax patient." (Nov. 3, 2010 Trial Tr. 413:5 - 10; *see also id.* at 470:2-24 (agreeing that Dr. Goss' letter to the editor of the Australian Dental Journal in October 2003 included the "first report of ONJ in the literature in the history of the world as it related to alendronate, someone using alendronate").) Dr. Goss also testified that Dr. Marx's September 2003 letter to the editor, reporting alleged cases of ONJ in patients taking intravenous bisphosphonates, was the only article he had seen reporting ONJ in any bisphosphonate users. (Trial Tr. 481:7-17.) Both of these publications occurred months after the Plaintiff's alleged March 2003 injury. In his letter to the editor, Dr. Goss stated that avascular necrosis in the Fosamax user was only a "potential drug-related cause," meaning that "[a]t that point in 2003," causation was unproven. (Trial Tr. 470:2-11.)

Plaintiff attempted to claw back at the state of the knowledge in March 2003 through the testimony of Dr. Parisian, who has no expertise whatsoever in jaw issues. (*see* April 21, 2010 *Maley* Trial Tr. 254:7-16 ("I'm not going to let her testify because she's not an expert on osteonecrosis of the jaw. . . . But I'm not going to let her say it's osteonecrosis of the jaw, because she doesn't know what osteonecrosis of the jaw is.").) Plaintiff merely placed a few

adverse event reports ("AERs") in front of Dr. Parisian, elicited no testimony about the specifics of those AERs, and generally asked Dr. Parisian to opine about what Merck should have done in light of those reports. In fact, none of the AERs Merck received prior to October 2003 reported osteonecrosis or dead bone in the jaw.

Indeed, some of these AERs actually reported bone growth, not bone death, in the jaw. (Tr. 796-797; Ex. 1.0922B, 1.0971, Ex. 1.2641.) Dr. Parisian conceded that these bone growth events can occur in the human mouth. (Tr. 797.) The jury heard no expert opinion that these bone growth events, or any of the other handful of AERs admitted through Dr. Parisian, made it foreseeable in 2003 that Fosamax presented a risk of ONJ.[9]

Therefore, Plaintiff's design defect claims fail as a matter of law because Plaintiff has not established that the risk of ONJ from Fosamax was foreseeable in March 2003.

9. Plaintiff has not established that the risks of Fosamax outweigh its benefits for its intended patient populations as a whole.

Plaintiff claims that Fosamax's risks outweigh its benefits for some, but not all, of the patients for whom it is indicated. While the Florida Supreme Court has not squarely addressed this issue, decisions from the Eleventh Circuit, Florida intermediate appellate courts, and courts applying analogous law from other jurisdictions all agree that at a minimum the risk/benefit analysis must be based on the benefits of the product as a whole, and not on the subjective viewpoint of any specific user:

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9. None of the other AERs admitted through Dr. Parisian reported jaw bone death. (See Pl.'s Ex. 1.2104 (xerostomia, i.e., dry mouth); Pl.'s Ex. 1.2637 (change in color tone of gingival tissue); Pl.'s Ex. 1.2640 ("red colored gingiva"); Pl.'s Ex. 1.0963 ("bone loss and 'change'"); Pl.'s Ex. 1.0970 (oral ulcerations from which patient recovered); Pl.'s Ex. 1.0974 ("teeth root problems" and "jaw mass"); Pl.'s Ex. 1.2705 (dental implant failure). As a matter of law, such a miniscule number of adverse event reports out of millions of uses of Fosamax are insufficient to prove that the risk of ONJ was foreseeable. See *Stupak v. Hoffman-La Roche, Inc.*, No. 07-15980, 2009 WL 1616713, at *5 (11th Cir. June 10, 2009) ("Seventeen such inconclusive case reports (out of millions of Accutane prescriptions) is simply insufficient to support an allegation that Roche knew or should have known that Accutane could cause suicide without premonitory symptoms.")).

- The Eleventh Circuit, applying Florida law, has stated "The defectiveness of a design is determined based on an objective standard, not from the viewpoint of any specific user." *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999);

- The Florida intermediate appellate courts repeatedly cite the Third Restatement of Torts in design defect cases,[10] and the Third Restatement provides that a prescription drug is not defectively designed unless the risks outweigh the benefits for all patients. *See* Restatement (Third) Torts: Products Liability § 6(c) (1998);[11] and

- Other states applying the risk/benefit test do not focus solely on a specific user or benefit, but instead also consider "the product's utility to the public as a whole." *See, e.g.*, *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 735 (N.Y. 1995); *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 260 (Ill. 2007); *Vautour v. Body Masters Sports Indust. Inc*., 784 A.2d 1178, 1182 (N.H. 2001) *American Tobacco Co. v. Grinnell*, 951 S.W.2d 432 (Tex. 1997); *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410, 414 (Colo. 1986); *O'Brien v. Muskin Corp.*, 463 A.2d 298, 304 (N.J. 1983).

Plaintiff has presented no evidence that Fosamax's risks outweigh its benefits for its indicated patient populations as a whole. As a result, Merck is entitled to judgment as a matter of law.

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10. *See Agrofollajes, S.A. v. E.I. Du Pont Nemours & Co., Inc.*, Nos. 3D07-2322, 3D07-2318, 3D07-1036, 2009 WL 4828975, *21 (Fla. 3d Dist. Ct. App. Dec. 16, 2009) (reversing jury verdict based on "consumer expectations" test because Third Restatement rejects that test); *Kohler Co. v. Marcotte*, 907 So.2d 596, 599 (Fla. 3d Dist. Ct. App. 2005) (relying on Third Restatement as setting forth proper test for design defect cases); *Accord Warren v. K Mart Corp.*, 765 So.2d 235, 237-38 (Fla. 1st Dist. Ct. App. 2000) (same). Florida courts have also relied on the Third Restatement in other contexts. *Sta-Rite Indus*. 909 So.2d at 904 n.4 ; *Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So.2d 1133, 1139 (Fla. 4th Dist. Ct. App. 2002); *Burch v. Sun State Ford, Inc.*, 864 So.2d 466, 472 (5th Dist. Ct. App. 2004). Decisions from state intermediate appellate courts are "not to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise." *City of New York v. Golden Feather Smoke Shop*, 597 F.3d 115, 126 (2d Cir. 2010).

11. Under the Third Restatement, Merck is entitled to judgment as a matter of law because Plaintiff conceded at trial that Fosamax's benefits exceed its risks for some patients. (*See, e.g.*, Tr. 1691:23 – 1692:4.

10. Merck is entitled to judgment as a matter of law on Plaintiff's negligence claim because she has not offered any evidence that a different design for Fosamax would have prevented her injury.

It is black letter law that "negligence in the air . . . will not do." *Palsgraf v. Long Island R. Co.*, 248 N.Y. 339, 341 (1928) (Cardozo, C.J.) ("Proof of negligence in the air, so to speak, will not do."). Plaintiff must go further and prove that any alleged negligence actually caused her injury. *See, e.g.*, *Estate of McCall v. U.S.*, 663 F. Supp.2d 1276, 1289 (N.D. Fla. 2009) (noting that in negligence cases, "to demonstrate proximate cause, the plaintiff must show that what was done or failed to be done probably would have affected the outcome or that the injury more likely than not resulted from the defendant's negligence") (quotation and citation omitted).

While Dr. Parisian (incorrectly) alleges that the receipt of a handful of non-ONJ AERs should have prompted Merck to conduct an ONJ study, neither she nor any other expert testified that the conduct of such a study or adopting a different method for safety surveillance would have resulted in a different design for Fosamax that would have avoided her injury. Put simply, Plaintiff has not established that any negligence on Merck's part was the proximate cause of her injury.

11. Merck is entitled to judgment as a matter of law based on Florida's government rules defense.

Under the government rules defense, Merck is entitled to a presumption that Fosamax was *not* defective, but instead was safe and effective for the purposes for which it was approved by the FDA. *See* Fla. Stat. Ann. § 768.1256.

12. Merck is entitled to judgment as a matter of law because Plaintiff's claims are preempted by federal law.

Merck is also entitled to judgment as a matter of law because Plaintiff's entire case is preempted. Conflict preemption applies "when compliance with both state and federal law is impossible, or when the state law 'stands as an obstacle to the accomplishment and execution of

the full purposes and objective of Congress.'" *California v. ARC America Corp.*, 490 U.S. 93, 100-101 (1989), (citations omitted). Plaintiff's claim presents exactly the type of conflict that federal preemption principles were designed to prevent – the FDA has determined, applying federal law, that Fosamax can be on the market and used for its indicated purposes because it is safe and effective, and Plaintiff seeks to use state tort law to contradict that finding.

CONCLUSION

For the foregoing reasons, the Court should enter a directed verdict as to all remaining claims in this case.

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Respectfully submitted,
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